

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Carl E. Fabian

Group Art Unit: 3761

Serial No.: 10/650,376

Examiner: Michael G. Bogart

Filed: August 29, 2003

For: **RADIOPAQUE MARKER FOR A SURGICAL SPONGE**

Docket No.: 0018-13

231 Somerville Road
Bedminster, NJ 07921
March 27, 2008

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 CFR 1.132

I, Carl E. Fabian, hereby declare that:

1. I received my B.S. degree from Cornell University in June, 1956, and my M.D. degree from the State University of New York, Downstate Medical Center in Brooklyn, in June, 1960. During medical school I was awarded membership in the Alpha Omega Alpha medical honor society and was awarded a scholarship for medical study abroad at Guys Hospital in London. I completed my general medical internship at Kings County Hospital, Brooklyn, New York, in June, 1961. I served my radiology residency at the same Hospital from July, 1961, through June, 1964, during which I was appointed chief resident and assistant instructor in radiology from 1963 through 1964. Upon completion of my residency, I joined the faculty of the Stanford University Medical School as an instructor in radiology. I served in the U.S. Army Medical Corps during 1966-1968 as a physician stationed in Panama.
2. Following my military medical service, I entered private practice in radiology in Miami, FL, in 1968. As part of my medical practice, I have maintained a teaching

affiliation with the University of Miami Medical School, instructing radiology residents in the interpretation of x-rays. I hold the rank of Voluntary Professor of Radiology.

3. As a radiologist, I hold Board Certifications awarded by the American Board of Radiology and the American Board of Nuclear Medicine and am a Fellow of the American College of Radiology.

4. I have published approximately 12 papers in medical journals relating to clinical radiology and am an inventor or co-inventor of 18 U.S. Patents, of which 17 of the patents concern radiological imaging techniques and related equipment for medical applications.

5. By virtue of my medical training and practice experience, I am generally familiar with the use of surgical sponges in carrying out surgical procedures in a hospital or other similar clinical setting. These sponges typically range in size from about 4 x 4 inches to 18 x 18 inches and are usually frequently made of loosely woven cotton. During surgery, they are routinely used for numerous purposes, including: packing spaces to maintain internal organs in their appointed places; protecting various organs while other nearby structures are treated; and to absorb blood and other bodily fluids that would otherwise block the surgeon's clear view of the operating field. As many as twenty or more such sponges are often required during a procedure. These sponges must be removed before completion of the surgery, or highly adverse, and potentially fatal, complications including infection almost certainly will ensue.

6. During the course of my radiology practice, I have encountered multiple instances in which surgical sponges were inadvertently left within patients during surgical procedures and I was engaged to use x-ray techniques to confirm the presence and location of the sponges, to facilitate appropriate follow up surgical removal of these

objects. These specific experiences, along with my general knowledge of the radiological literature, have acquainted me with the difficulties encountered in using x-rays to locate retained surgical items and implements in actual clinical practice and the serious adverse, and potentially fatal, consequences that attend failure to promptly locate and surgically remove these foreign items. These experiences also led me to consider ways by which the likelihood of detecting such retained sponges or other surgical items might be improved.

7. I am the inventor of the above-identified application Serial No. 10/650,379, and have read the application and the Office Action dated November 29, 2007, therein. I have also read the amended claims 1-6, 11, 13-14, and 17-19, which were submitted with the applicant's amendment entered August 31, 2007.

8. I have read US Patent No. 6,777,623 to Ballard and US Patent No. 3,911,922 to Kliger, which were cited in the November 29 Office Action.

9. In my considered opinion based on my knowledge and experience, the term "radiopaque," as used in the context of medical radiology, would be understood by a person having ordinary skill, as being a relative term in a continuum, not an absolute descriptive adjective. That is to say, the skilled person would regard a "radiopaque object" as being one that would absorb a sufficient amount of incident x-radiation to make it visible on an x-ray film or other like x-ray image taken within the range of conditions reasonably expected during normal clinical practice.

10. In my considered opinion based on my knowledge and experience, most conventional surgical sponges are tagged with an embedded thread or strip impregnated with barium sulfate that provides some degree of radiopacity. An experienced radiologist would know that the character and visibility of a radiographic image of such a tagged

sponge within a patient is dependent on multiple factors, including *inter alia* the characteristics of the incident x-ray beam, the duration and strength of exposure, the sensitivity of the x-ray film or other imaging medium, and the configuration of the sponge and its positioning relative to other internal body structures and foreign items intentionally present, such as tubing, catheters, pacemakers, or other implanted devices.

11. In my considered opinion based on my knowledge and experience, an experienced radiologist would know that the radiopacity of a barium sulfate-impregnated thread or strip is substantially lower than the radiopacity of steels or other metals typically employed in surgical implements and like objects used in surgical practice, so that an x-ray image of a barium sulfate-impregnated thread or strip would provide a much less distinct image than that of a typical metal object.

12. In my considered opinion based on my knowledge and experience, the presence of barium sulfate-impregnated strip in a surgical sponge, such as those disclosed for the sponge taught in US Patent 3,911,922, is insufficient to assure fully reliable detection of the sponge in a medical x-ray image within the full range of conditions a radiologist would reasonably expect in clinical practice. More specifically, a skilled radiologist would know that the level of contrast in an x-ray image of such a sponge is, in some cases, insufficient to permit the sponge to be identified and localized. The radiologist would know that image of such a sponge would be “burned out” in a very dark (heavily exposed) film, so that no recognizable image would be perceptible even to a skilled practitioner, let alone to a person having less skill and experience in scrutinizing x-ray images. As a result, in an ordinary clinical setting, the sponge would in many cases be missed during x-ray examination.

13. In order to confirm the functionality of surgical sponges of the type provided by my invention, I carried out experimental tests using a conventional, commercially available, 14 x 14 inch laparotomy surgical sponge made of loosely woven cotton that included a radiopaque barium sulfate-impregnated strip of fabric. I modified the sponge to further include three small metal BBs placed in a generally triangular, substantially abutting configuration. These BBs were of the type commonly used for sport as the ammunition for an air rifle, in the form of a sphere about 4 mm in diameter and composed of steel with a thin copper surface layer. They were situated in a small cotton envelope attached to the modified sponge.

14. In order to simulate the x-ray examination procedure needed to detect a sponge inadvertently retained after surgery, I placed the modified sponge substantially flat on the surface of my abdomen while in a supine position. An assistant took a series of anterior-posterior x-rays of my abdomen using conventional medical x-ray equipment at under various exposure conditions that would typically be used in clinical practice. This configuration would be expected to be rendering the radiopaque, barium sulfate-impregnated strip in the sponge most readily detectable, since the sponge was fully flat and unfolded in a plane generally parallel to the plane of the x-ray film during exposure.

15. I examined the developed x-ray films obtained as described in §14. At relatively low exposure, both the barium sulfate-impregnated thread and the three metal BB spheres were readily apparent, along with the expected anatomical features, such as the pelvis and lower vertebrae. However, in a very heavily exposed film, the three metal BB spheres was still clearly apparent, while neither the barium sulfate-impregnated strip nor the most radiologically dense anatomical features (e.g., the bony spine and pelvis) could

be visualized. Copies of the low exposure and high exposure x-ray films are appended to this declaration as Exhibits I and II, respectively.

16. In my considered opinion based on my knowledge and experience, the finding set forth in §15 confirms that a surgical sponge constructed in accordance with my invention gives rise to a visually distinctive x-ray image even under conditions in which a conventional sponge including a barium sulfate-impregnated strip did not result in any perceptible x-ray image. For example, an actual retained sponge would almost invariably not be flat, but rather folded or wadded, and disposed in a random orientation, so that the conventional radiopaque strip would have a much less regular and predictable shape.

17. In my considered opinion based on my knowledge and experience, a surgical sponge of the type disclosed by the Ballard patent and having a single spherical, radiopaque object, would not provide a radiological image that unambiguously has a distinctive, visually recognizable shape. It is known in clinical practice that isolated objects generally termed "foreign bodies" are frequently present in a patient's body. In some instances, foreign bodies having a generally spherical shape, such as buckshot, birdshot, or like projectile from firearms, are present. Objects giving rise to a small, generally spherical appearance on an x-ray may also arise from a surgical dressing or otherwise overlie a postoperative patient. On the other hand, based on my clinical experience, the presence of multiple, contiguous spherical objects would virtually never be encountered. As a result, it is my considered opinion that the presence in an x-ray image of the multiple, contiguous spherical objects of my sponge would be unique and distinctive, making it far less likely that such an image would be overlooked or missed by a skilled practitioner, compared to an image containing a single, isolated spherical

feature, or even multiple spherical features not having a distinctive geometrical arrangement.

18. In my considered opinion based on my knowledge and experience, a surgical sponge of the type disclosed by the Kliger patent would not provide a radiological image that has a distinctive, visually recognizable shape. Instead, the presence of a large number of generally linear marker elements composed of threads including finely divided, x-ray absorbent powder and disposed in a random arrangement throughout the Kliger sponge would produce an image that even an experienced radiologist would not be able to unambiguously identify even under the best circumstances, especially if the sponge is folded, crumpled, or similarly deformed, as frequently encountered in clinical practice. Furthermore, such a "radiopaque" marking would almost certainly be "burned-out" and rendered invisible with a heavier x-ray exposure.

19. In my considered opinion based on my knowledge and experience, the intensity of the x-ray beam needed to implement a sponge-counting system of the type disclosed by the Ballard patent would be far lower than that typically employed in a clinical setting for x-ray examination of a human subject, because the beam in the Ballard system would not need to penetrate the full thickness of the subject. Rather, the beam in the Ballard system would only need to penetrate the thickness of the sponge disposal receptacle and the discarded sponges already present therein. As a result, it is my opinion that the difficulty in reliably locating a sponge in x-ray films of varying exposure described in §10 above would not ordinarily arise in the operation of the Ballard system.

20. In my considered opinion based on my knowledge and experience, a sponge-counting system of the type disclosed by the Ballard patent could not reliably be used with sponges of the type disclosed by the Kliger patent. The Ballard system relies on the

production of a unique and unambiguous x-ray signature by each of the sponges being discarded in the appointed receptacle. On the other hand, the Kliger sponges have an indeterminate arrangement and number of x-ray absorbing elements, so that a radiological image of an assemblage of Kliger sponges could not be unambiguously interpreted to yield a definite count of sponges. The lack of a definite count would render the Ballard counting system inoperative. As a result, it is my opinion that a skilled person would have motivation not to use the sponges provided by Kliger in the sponge-counting system provided by Ballard.

21. In my considered opinion based on my knowledge and experience, a modification of the Ballard sponge in accordance with the Kliger teaching would result in a sponge having an indeterminate plural number of radiopaque elements randomly dispersed throughout the sponge. As a result, such a modified sponge would not give rise to a radiographic image providing a distinctive, visually recognizable shape. In addition, such a sponge could not successfully be used with the Ballard sponge-counting system, since the indeterminate number of radiopaque elements in each sponge would preclude any means of counting the number of sponges deposited in a receptacle, as required for the Ballard counting function.

22. In my considered opinion based on my knowledge and experience, a sponge-counting system of the type disclosed by the Ballard patent is structured in a manner that renders it inherently incapable of detecting a sponge present in a surgical wound in an actual patient, regardless of whether the sponge is of any type disclosed in the Ballard or Kliger patents or constructed in accordance with the combined teaching of those patents. Specifically, the Ballard patent does not disclose any system configured to be able to impinge an x-ray appropriately directed to the patient's body. Rather, as shown in Fig. 2

of the Ballard patent, the system includes an x-ray source impinging only on a container appointed to receive and count sponges discarded after use. The Ballard patent further fails to disclose or suggest any system providing an x-ray beam that has the correct energy and intensity to provide a proper x-ray exposure to yield a suitable x-ray image of a patient's anatomy, including any retained surgical implements.

I hereby declare that the foregoing statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: MARCH 27, 2008

By: Carl E. Fabian MD
Carl E. Fabian, MD



Exhibit I

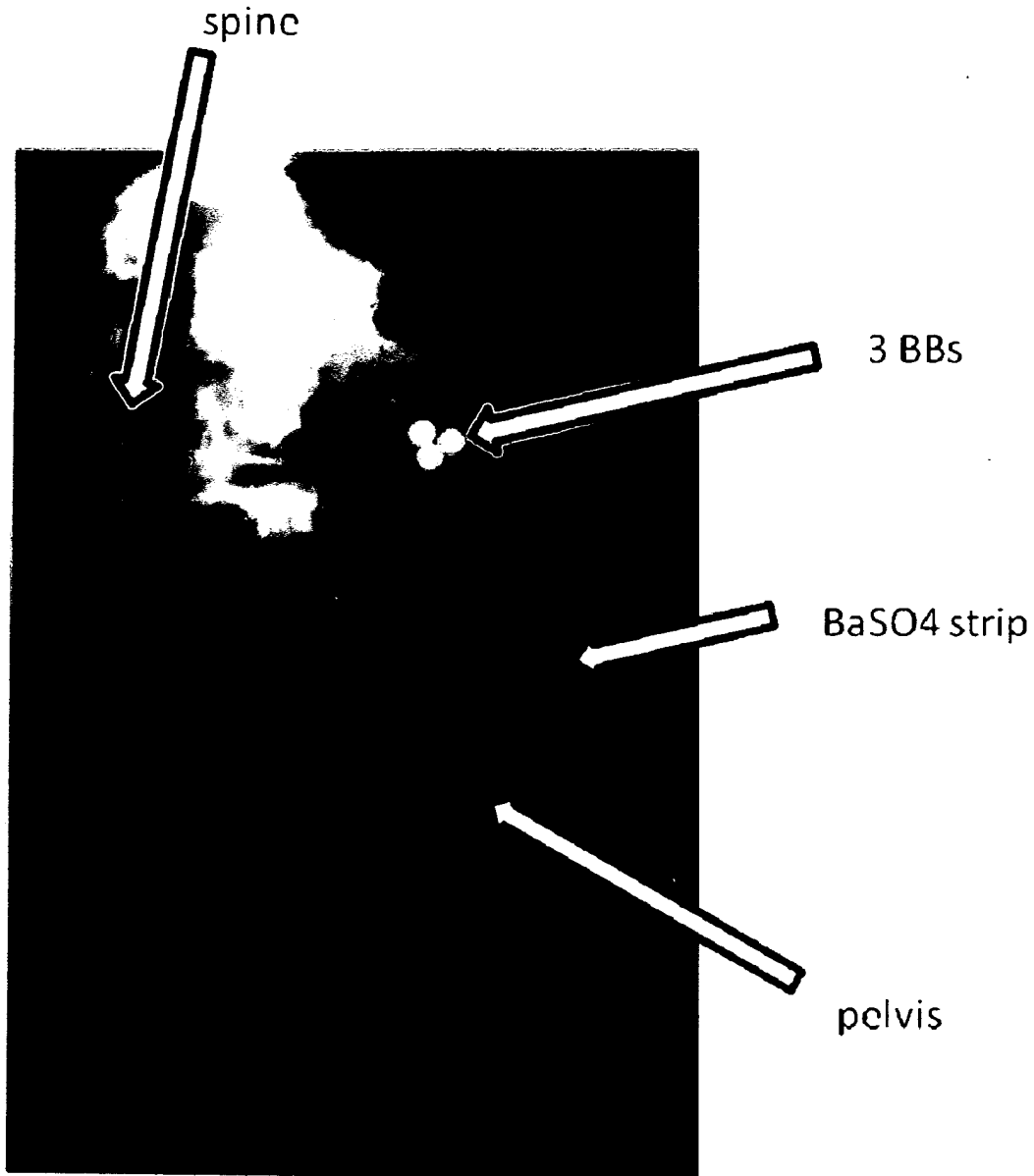
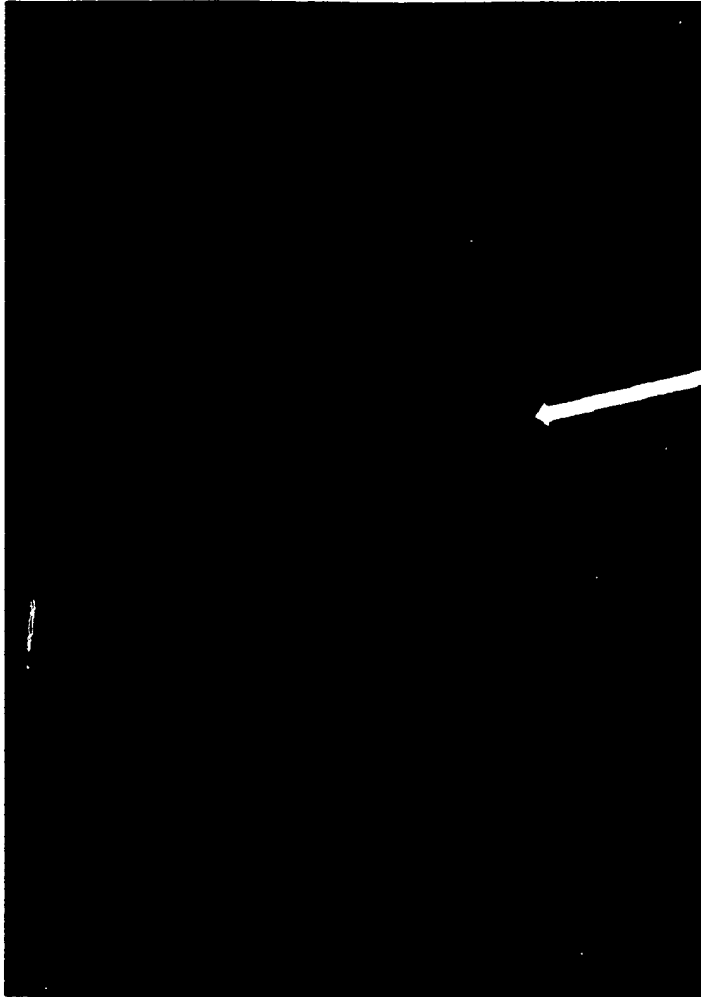


Exhibit II



3 BBs